REMARKS

Claims 1-21 are pending in the present application.

Restriction Requirement/Election of Species

Claims 1-21 are subject to a Restriction Requirement under 35 U.S.C. §§ 121 and 372 for reciting inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. (*See*, Office Communication, at page 2). Applicants traverse as hereinafter set forth.

The Examiner has required election in the present application between:

Group I, claims 1-13 and 21, drawn to a replicon RNA, comprising a nucleotide sequence containing at least the 5' untranslated region, the nucleotide sequence encoding NS3 protein, NS4A protein, NS4B protein, NS5A protein, and NS5B protein and the 3' untranslated region on the genomic RNA of hepatitis C virus (HCV) of genotype 2a, and a replicon-replicating cell comprising said replicon RNA;

Group II, claims 14 and 15, drawn to a method of producing an HCV replicon RNA and a method of producing an HCV viral protein from a replicon-replicating cell, comprising extracting replicon RNA or obtaining viral protein from said cell;

Group III, claim 16, drawn to a method of screening for a substance promoting or suppressing replication of HCV, comprising culturing a replicon-replicating cell in the presence of a test substance and detecting the replication of a replicon RNA; and

Group IV, claims 17-20, drawn to a method of increasing the replication efficiency of an HCV replicon RNA, comprising introducing a replicated replicon RNA into a non-parental cell to produce a new replicon-replicating cell; and a method of producing an HCV replicon RNA

having increased replication efficiency, comprising detecting a nucleotide or an amino acid mutation associated with an increased replication efficiency, and introducing said mutation into a replicon RNA.

For the purpose of examination of the present application, Applicants elect, with traverse, Group I, Claims 1-13 and 21.

The Examiner has further required a restriction between SEQ ID NOS: 1, 2, 3, 5, 9, 10, 11 and 12. The Examiner states that Applicants are required to choose a single, specific SEQ ID NO for the replicon RNA, i.e. SEQ ID NOS: 1, 2, 3 or 5. The Examine has also required that Applicants select either SEQ ID NO: 9 or 10 and either SEQ ID NO: 11 or 12. In response thereto, Applicants elect as follows:

SEQ ID NO: 1 as the replicon RNA;

SEQ ID NO: 9 as the 5′ untranslated region; and

SEQ ID NO: 11 as the 3′ untranslated region.

The Examiner is respectfully reminded according to MPEP § 1893.03(d), that if the Examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable, the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that

requires all the limitations of an allowable process claim, should be rejoined. (*See*, MPEP § 821.04 and § 821.04(a)). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

Further, Applicants believe the present restriction is overly burdensome and not in accordance with the MPEP. All of the claims as presently recited are based upon a single general inventive concept under PCT Rule 13.1. The PCT administrative authority has already considered the present invention to possess unity, and to directly contest this consideration by the PCT administrative authority is improper. The fact that the species DNAs contain different patentable nucleotide sequences does not mean that the DNAs are of a different general inventive concept.

Particularly, Applicants refer to MPEP § 1850, which states as follows:

> "Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims." (emphasis added)

Accordingly, under the PCT administrative instructions set forth in the MPEP, it is improper in a Restriction Requirement to group separately, dependent claims, which are directed to specific embodiments and/or particular sequences. The Examiner has thus required an additional restriction which violates these directives. Reconsideration and withdrawal of the restriction as to the narrowing of the present invention to particular sequences recited in dependent claims, are respectfully requested.

Finally, according to MPEP § 803, if the search and examination of an entire application can be made without a serious burden, the Examiner *must* examine it on the merits, even though it includes claims to independent or distinct inventions. Applicants do not believe the

examination of the entire application would be an undue burden. The Examiner has not provided a basis for the assertion that the specific sequences according to the present invention are independent and patentably distinct. The Examiner's statements are legally insufficient and therefore do not shift the burden of selecting a sequence to the Applicants.

For this additional reason, Applicants respectfully request reconsideration and withdrawal of the restriction requirement to a particular sequence or set of sequences.

Species Election

The Examiner has also required an election in the present application as follows:

- an election to a specifically named marker gene or a specifically named reporter gene (claim 2), as recited on pp. 16-17 of the specification;

- an election to a specifically named liver-derived, uterine cervix-derived or fetal kidney-derived human cell, and either Huh7, HepG2, IMY-N9, HeLa or 293 cell, commensurate with the scope of human cell, as recited in claims 8 and 9; and

- an election to a specific replicon RNA mutation corresponding to SEQ ID NO: 1, as recited in claim 21, (a) to (u).

For the purpose of beginning examination of the present application, Applicants elect, with traverse, as follows:

Marker or reporter gene: neomycin resistance gene;

Cells: human liver-derived cell for claim 8, and Huh7 cell for claim 9; and

Replicon RNA mutation: (b) for claim 21.

Applicants assert that claims 1-13 and 21 are directed to the elected species.

Applicants are aware that upon the allowance of a generic claim, i.e. any one of claims 1-21, all of which are identified by the Examiner as being generic, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R § 1.141. That is, according to US practice, Applicants understand that they must elect a single species for further prosecution. However, once the Examiner finds allowable subject matter based upon the single species elected, the Examiner is required to then expand the search to include a reasonable number of additional species. As provided in the M.P.E.P. at § 809.02 and stated by the Examiner:

> *Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).*

As grounds for the traversal, Applicants assert the same reasoning applied above, with respect to the restriction requirement. That is for the same reasons, Applicants believe the Examiner's further restriction is not sufficiently supported, not in accordance with the dictates of the MPEP and does not qualify as an undue burden based on the comments provided by the Examiner.

CONCLUSION

If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By_____
Andrew D. Meikle
Registration No.: 32,868
BIRCH, STEWART, KOLASCH & BIRCH, LLP
8110 Gatehouse Road
Suite 100 East
P.O. Box 747
Falls Church, Virginia 22040-0747
(703) 205-8000
Attorney for Applicants